ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 162

[OPP-30003B; PH FRL 1619-2]

State Registration of Pesticides To Meet Special Local Needs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes final rules for the registration of pesticides by the States to meet special local needs, as authorized by sec. 24(c) and 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended [FIFRA] (sec. 22 and 23, Pub. L. 95-396, 92 Stat. 819; 7 U.S.C. 136 et seq.). This rule clarifies the scope of the authority granted to the States by the statute, describes registration procedures for States, and establishes procedures for EPA's exercise of its statutory power to disapprove certain State registrations and to suspend State registration authority.

EFFECTIVE DATE: This rule will not take effect before the end of 60 calendar days of continuous session of Congress after the date of publication of this rule. EPA will publish a notice of the actual effective date of this rule. See Supplementary Information for further details.

FOR FURTHER INFORMATION CONTACT: P. H. Gray, Jr., Sec. 24(c) Working Group Leader (TS-770-M), Office of Pesticide Programs, Office of Pesticides and Toxic Substances, Environmental Protection Agency, 1401 M St. SW., Washington, D.C. 20460, 202-472-9400.

SUPPLEMENTARY INFORMATION: These rules will be designated as §§ 162.150 through 162.155, Subpart D, Part 162, Title 40 of the code of Federal Regulations.

These rules were tentatively designated as Subpart B and published as a proposed rule for public comment on August 7, 1979 (44 FR 46414). Subsequent to the publication of the proposed rules, the Section 24(c) Working Group was notified that Subpart B would be designated for future amendments to regulations under section 3 of FIFRA. Accordingly, the final sec. 24(c) regulations will be designated as Subpart D of Part 162.

Subpart D replaces the proposed rules establishing the Interim Section 24(c) Program published on September 3, 1975 (40 FR 40538), as well as the Transitional Section 24(c) Policy statement signed on October 5, 1978, by the Deputy Assistant Administrator for Pesticide Programs [44 FR 46422 *et seq.*].

Background

On September 30, 1978, the Federal Pesticide Act of 1978 (Pub. L. 95-396, 92 Stat. 819) amending the Federal Insecticide, Fungicide, and Rodenticide Act, (FIFRA) went into effect. Among the sections of FIFRA which were substantially modified is sec. 24(c) (sec. 2 of Pub. L. 95-396), which authorizes the States to register "additional uses of federally registered pesticides to meet special local needs." The changes made in sec. 24(c) by the Federal Pesticide Act are described in the preamble to the proposed sec. 24(c) regulations published in the Federal Register of August 7, 1979 (44 FR 46414).

Comments on the proposed rules were received from approximately 15 sources, including members of the pesticide production industry, pesticide user groups, environmental groups, and several States. These comments are available for public inspection at the Office of the Documents Control Officer, Management Support Division (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-447, 401 M St., SW, Washington, D.C. 20460.

After consideration of all comments received, EPA has made several, relatively minor, changes in Subpart D. Most of these revisions were made to clarify sec. which apparently were unclear to some readers, or in response to comments made on specific issues discussed in the preamble to the proposed rule. Both the significant relevant comments and the significant changes in the rule are discussed below.

Comments

General

Comments referred to in this preamble are numbered 1(30003A) through 17(30003A) in EPA's public access file. For the purposes of discussion in this preamble, the comments are referred to as numbers 1 through 15A, corresponding to the official numbering system.

Of the comments received, seven comments [nos. 3, 6, 8, 10, 11, 15, and 15A] were received which were generally, or entirely, supportive of the proposed regulations. These included comments from the Ohio Department of Agriculture, Dow Chemical Co., the Georgia Department of Agriculture and Cooperative Extension Service, and the Virginia and Ohio Farm Bureau Federations.

Four commenters responded to the suggestion contained in the preamble to the proposed rules that State registrations are limited by sec. 24(c) to products formulated only from manufacturing-use products (technical grade materials) registered under sec. 3 of FIFRA (44 FR 46415). Two commenters (nos. 4 and 5) favored this interpretation of sec. 24(c), while the third commenter (no. 7) opposed it as unnecessary. The fourth commenter (no. 1) favored the idea of a limitation, but suggested that States also be allowed to register products formulated from end-use products registered by EPA.

EPA has concluded that sec. 24(c)(1) was intended to limit State registration of new end-use products to those whose active ingredients are present because of the use of federally-registered products. Accordingly, a new § 162.152(b)(2)(ii) has been added to clarify this limitation.

In effect, this provision will permit States to continue to register new end-use products which are formulated from one or more manufacturing-use or end-use products previously registered by EPA under sec. 3 of FIFRA. Reformulation of a product labeled for end-use, for the purpose of manufacturing a new product, is generally a use not permitted by the original product's labeling. Ordinarily, this would technically be a use inconsistent with the original end-use product's labeling and a violation of sec. 12(a)(2)(G) of FIFRA. However, EPA has determined that such a practice is consistent with the purposes of FIFRA, at this time, and, under sec. 2(ee) of FIFRA, that it is not prohibited by the Act. This practice—registration of reformulated end-use products—is also consistent with EPA's past practice for registration under sec. 3.

Nonetheless, the Agency recognizes that this policy under sec. 3 and sec. 24(c) may cause difficulties in the application of the data requirements for registration under sec. 3 of the Act. For example, in EPA's proposed data guidelines, some data requirements which apply to manufacturing-use products do not apply to end-use products with particular use patterns. In addition, reformulation of end-use products could create opportunities for evasion of the data compensation provisions of sec. 3(c)(1)(D) of the Act.

Accordingly, EPA is now in the process of re-evaluating its policy regarding registration of reformulated end-use products under sec. 3. If EPA concludes that the disadvantages of registering such products outweigh the advantages, then EPA's policy under sec. 3 will be modified accordingly. Thereafter, any reformulation of end-use products, for distribution or sale, not in

conformance with the products' labeling or EPA policy would be a violation of sec. 12(a)(2)(G) of FIFRA, and registration of such a product would not be consistent with the purposes of FIFRA. Therefore, since sec. 24(c)(1) requires State registrations to be issued "in accordance with the purposes of the Act," State registration of end-use products must be carried out consistently with EPA's current and future policy on registration under sec. 3. Section 162.152(b)(2) (ii) of the regulations will be revised to clarify any limitations on State authority when, and if, EPA modifies its policy on reformulation of end-use products.

It should be noted that § 162.152(b)(2)(ii) will effectively bar an applicant for State registration from producing active ingredients for his own use in formulating end-use products, unless he has already obtained a section 3 registration for the ingredient as a manufacturing-use product. In addition, § 162.152(b)(1)(iv) and § 162.152(b)(2)(iii) [§ 162.152(b)(2)(ii) in the proposed rules] expressly prohibit State registration of new manufacturing-use products and of amendments to federally registered manufacturing-use products.

Three commenters commented on proposed § 162.153(h)(4)(i). One commenter (no. 7) stated, incorrectly, that that section authorized EPA to request data used for unreasonable adverse effects determinations from a State for any registration issued under sec. 24(c) of FIFRA. The other commenters (nos. 1 and 8) responded to the question posed in the preamble to the proposed rule (44 FR 46417) on whether § 162.153(h)(4) should be revised to authorize EPA to request data on unreasonable adverse effects in every case where States are required by § 162.153(c) to conduct such a hazard review. Those commenters, including the Wyoming Department of Agriculture, suggested that § 162.153(c) and (h)(4) be made consistent.

In accordance with these comments, and for the reasons set forth in the preamble to the proposed rule, § 162.153(h)(4) has been revised to authorize EPA to request, when appropriate, hazard data from the States in all situations covered by § 162.153(c). This data may be required in such cases to enable EPA to determine if an imminent hazard is created by the registration.

With regard to another question raised in the preamble to the proposed rule on excluding voluntary cancellations from the prohibition in § 162.153(b) against State registrations of cancelled uses, three comments were received. Two commenters (nos. 8 and 14) suggested that all voluntarily cancelled uses should be included in the prohibition.

One commenter (no. 1) favored allowing States to register a use voluntarily cancelled under section 3 if such cancellation was not preceded by a notice of intent to cancel. However, the commenter went on to suggest that in such cases the State must first determine the reason for voluntary cancellation, since a registrant may voluntarily cancel a registration because of health or safety concerns, even though EPA has not issued a notice of intent to cancel.

EPA has considered these issues at length and has decided that section 24(c)(1) was not intended to apply in all cases of voluntarily cancelled registrations, since some registrations may have been cancelled merely for reasons of convenience. However, voluntary cancellations made by a registrant subsequent to a notice of intent to cancel by EPA are in the same general class as cancellations actually made by the Administrator for health and safety reasons. Therefore, such cancellations are covered by sec. 24(c)(1). Accordingly, § 162.152(a)(3) has been revised to specifically include such voluntarily cancelled registrations.

Where no notice of cancellation is involved, the reason for voluntary cancellation may not be apparent. In such cases, EPA may have access to facts that the States do not, and which States should consider before deciding whether to issue a registration under section 24(c). Therefore, § 162.152(b)(1)(iii) and (2)(iv) have been expanded slightly to require States to consult, informally, with EPA before registering any use of a product for which federal registration has been voluntarily cancelled without a prior notice of intent to cancel by the Administrator.

On a related matter, one commenter (no. 4) suggested that § 162.152(b) should also require States to notify EPA prior to registration of any products which are not similar in composition to any pesticide registered under sec. 3. EPA does not feel that such an extension is necessary, given that § 162.153(c)(1)(i) requires States to determine that such a registration will not cause unreasonable adverse effects on man or the environment, and that EPA has authority to request underlying hazard data under § 162.153(1)(4) and to disapprove such registrations, if appropriate, under §162.154.

Definitions

Several commenters objected that several of the proposed definitions were intended to make "essentiality" a prerequisite for State registration, contrary to the intent of sec. 24(c)(2). One of these commenters (no. 7) claimed that the definition of "pest problem" under § 162.151(d) would lead to this result—in the case of desiccants, defoliants, and plant regulators—since that definition uses the word "requiring" when describing when such pesticides may be registered to correct a pest problem. EPA does not agree with this commenter's interpretation of the definition, and rejects any suggestion that EPA is trying indirectly to take any action forbidden by sec. 24(c). However, to avoid any confusion with regard to the meaning of the term "pest problem," § 162.151(d)(2) has been revised to state clearly that a pest problem may exist whenever use of a defoliant, desiccant, or plant regulator would be "appropriate."

Similarly, two commenters (nos. 2 and 16) claimed that the definition of "special local need" under § 162.151(i) would make essentiality a criteria for registration, since that section and § 162.153(b) require a State to determine "that an appropriate federally registered pesticide . . . is not sufficiently available" to meet the local need. EPA must also reject this interpretation of § 162.151(i). As the preamble to the proposed regulations stated (44 FR 46415, 46416), § 162.151(i) clearly leaves the States ample discretion to determine whether any pesticide registered under sec. 3 is both "appropriate" and "sufficiently available" to meet the local need. This discretion allows a State to register a pesticide which is not absolutely "essential," if, in the good faith exercise of its authority, the State determines that a federally registered pesticide is either not "appropriate" or is, for some reason, not "sufficiently available." On the other hand, § 162.151(i) leaves any State free to use lack of essentiality as a ground for denying State registration if the State feels that is appropriate. Therefore, the definition of "special local need" represents a reasonable compromise between the need to give States some direction as to how to determine whether a special local need exists, and the need to allow the States to exercise the discretion Congress intended them to have. No change in the definition is required.

Similarly, EPA must reject the suggestion of two commenters (nos. 9 and 15) who believe that § 162.153(b) should not give examples of what a State may consider as not involving a special local need. EPA again points out, as previously stated in the preamble to

the proposed rule (44 FR 46416), that § 162.153(b) leaves the States full discretion as to whether these examples should be used in a given case. EPA does not intend to second-guess the States in such matters but it does expect the States to use their discretion to make reasonable determinations under § 162.153(b), in order to prevent registrants from circumventing the requirements of sec. 3 of FIFRA. For this reason, EPA must reject another commenter's (no. 1) claim that registration in other States is a factor which should never be considered by a State under § 162.153(b). An obvious nationwide pattern of State registrations for a particular use should be considered by a State in determining whether a registrant is evading registration requirements under sec. 3. However, EPA cannot specify a number of States which can be used as a basis for drawing a line between local and national needs, as was requested by one commenter (no. 4). Such decisions must be made on a case-by-case basis.

On the other hand, EPA must reject the suggestion of two commenters (nos. 5 and 8) that the definition of "special local need" is too broad and allows the States too much discretion. As stated earlier, the current definition reflects Congress' intent to broaden State authority under sec. 24(c) and is consistent with the experience of EPA and the States under the original sec. 24(c).

Another commenter (no. 12), however, raised a valid question about the definition. That commenter asked whether economic factors, as well as considerations of quantity, location, transportation difficulties, and similar factors affecting the availability of federally registered pesticides, could be considered in determining that a "federally registered pesticide is not sufficiently available." EPA has considered this issue carefully and has concluded that economic factors may indeed be taken into consideration by a State in deciding whether or not an EPA-registered product is "sufficiently available."

On a similar topic, one commenter (no. 5) stated that the definition of "similar use pattern" under § 162.151(1) was too broad, and that EPA is required to write "standards" to define what is a similar use pattern. Another commenter (no. 13) claimed that the definition should have stated expressly that a change from terrestrial to aquatic applications is not considered a similar use pattern. EPA must reject both comments.

The definition of "similar use pattern" was intended to be broad, in accordance with the apparent intent of Congress that the term be interpreted in a way which would allow States to issue certain routine registrations free from EPA's disapproved authority in cases where the Agency has already considered the same or similar registrations under sec. 3 (see S. Rep. 95–1188, p. 51). Also, there is no need to write more specific standards to distinguish between similar and non-similar use patterns since § 162.151(h) can be easily applied to all situations likely to arise under sec. 24(c). Finally, it should be noted that changes from aquatic to terrestial applications, and vice versa, are "changed used patterns," as defined by 40 CFR 162.3(k), and are therefore expressly excluded from § 162.151(h), since § 162.3 is incorporated by reference in § 162.151.

Finally, another comment (no. 7) on the definition section of the proposed rule requested clarification of the definition of "federally registered," § 162.151(a). Specifically, the commenter asked if pesticides registered by a State prior to August 4, 1975, as described in EPA's Pesticide Enforcement Policy Statement No. 3, are considered "federally registered." Such registrations are not covered by § 162.151(a) since they were not registered by the Administrator of EPA, nor by the Secretary of Agriculture, and since such registrations are specifically excluded from the applicability of this rule by § 162.150(b).

The same commenter also asked whether a valid registration under sec. 24(c) sustains itself under the provisions of FIFRA. As stated in the preamble to the proposed rule (44 FR 46416), valid registrations under sec. 24(c) are subject to all provisions of FIFRA which come into effect after issuance of a registration, including provisions for continuing a federal registration.

State Registration Authority

Two commenters (nos. 4 and 16) objected generally that these rules would expand State registration authority beyond that granted by the original version of sec. 24(c), contrary to the intent of Congress. EPA must reject these comments for the reasons stated in the preamble to the proposed rule (44 FR 46414).

Another commenter (no. 5) stated specifically that sec. 24(c) does not authorize States to register new pesticide products, as provided by proposed § 162.152(b)(2). The commenter cited that absence of language in sec. 24(c) expressly authorizing such registrations, as well as certain portions of the Senate Committee on Agriculture, Nutrition, and Forestry Report on the Federal Pesticide Act of 1978, pp. 81, 169 (January 1979) which the commenter believes support its interpretation.

EPA has considered these points at length. In fact, similar arguments were exhaustively examined by EPA prior to the drafting of the proposed rule. However, it was concluded that, although the express language of sec. 24(c) could be interpreted as the commenter suggested, such an interpretation "would be inconsistent with Congress' general intent to broaden State registration authority * * *" (see preamble, 44 FR 46415), since such an interpretation would, in fact, remove authority which States clearly possessed under the original sec. 24(c). It is extremely unlikely that Congress intended such a result.

It should also be noted that, although the legislative history cited by the commenter tends to support the commenter's opinion, other, equally valid, examples of the legislative history of sec. 24(c) support EPA's interpretation (see, e.g., H.R. Rep. 95–1188, pp. 50–51, (September 12, 1978)). Therefore, that portion of the commenter's argument is not sufficiently persuasive.

In addition, EPA would point out that only one response was received on this issue, even though the preamble to the proposed rule clearly invited comment on EPA's interpretation. Therefore, this commenter apparently stands alone in objecting to § 162.152(b)(2), even though other members of the pesticide manufacturing industry might benefit economically if the commenter's suggestion were adopted by EPA.

Therefore, since the language of sec. 24(c) is subject to the interpretation given it in the proposed rules, since that interpretation is consistent with Congress' general intent, and since the legislative history of the section is not conclusive, EPA must reject this comment.

On a similar matter, another commenter (No. 16) stated his opinion that sec. 24(b) of FIFRA prohibits States from issuing registrations under sec. 24(c) for a pesticide use already registered under sec. 3, contrary to proposed § 162.152(c)(2). EPA rejects this comment on the grounds that it is based on an erroneous interpretation of sec. 24(b). That section merely prohibits States requiring changes in the labeling or packaging of products registered under sec. 3. It does not prohibit State registration of the use itself under sec. 24(c), even though the State registration may require the addition of supplemental labeling to the product. Such supplemental labeling is necessary to implement sec. 24(c), and its use is therefore "required under [the] * * *

Act" and is authorized by sec. 24(b). Those sections must be read consistently, and not in such a way as to negate each other.

With regard to limitations on State authority, one commenter (No. 5) suggested that the requirement in § 162.152(a)(2), as explained in the preamble to the proposed rule (44 FR 46415), for tolerances and clearances for food or feed uses should not apply to inert ingredients, by-products, and metabolites. The commenter claimed that such a requirement would be inconsistent with Agency policy with regard to registrations under sec. 3 of FIFRA. EPA must reject this comment since the requirement is, in fact, consistent with current Agency policy for federal registrations (e.g., 40 CFR Part 180). Although EPA does not always publish tolerances or other clearances for inerts, metabolites, and by-products, it always satisfies itself that nontoxicological problems will be caused by such compounds before registering a product. EPA believes that this policy, together with sec. 24(c)(3)'s express prohibition against State registration of pesticides for food or feed use without tolerances or exemptions under the FFDCA, justifies the limitation found in § 162.152(a)(2).

Another commenter (No. 4) criticized proposed § 162.152 (b) and (c), which permits State registration of uses of products for which other uses of the same product have been cancelled by EPA. The commenter implied that the States should not be allowed to register such uses, and that authority to do so would lead to State registration of many new uses of products like DDT over which EPA would have little or no control. This commenter has apparently overlooked the statement in the preamble to the proposed rule (44 FR 46415) which explained that the provisions in question were written to be consistent with the express language of sec. 24(c)(1). In addition, the commenter has overlooked the fact that § 162.152 (b) and (c) require States to consult with EPA prior to registering such uses. This prior consultation will allow EPA to discuss controversial applications with a State, and, where necessary, provide EPA with an opportunity to dissuade the State from issuing a potentially hazardous registration. In those cases where the State nevertheless issues a registration, EPA will at least have had sufficient prior notice of the State action to take whatever steps might be necessary and appropriate to prevent unreasonable adverse effects from occurring.

State Registration Procedures

One commenter (No. 4) requested that it be given direct notification of any sec. 24(c) registration issued for a use of a pesticide for which other uses of the same pesticide were cancelled after hearings in which the commenter had participated. EPA must reject this request for special notification since it would impose an unreasonable and unnecessary burden upon the Agency or the States. Since notice of all sec. 24(c) registrations will be regularly published in the Federal Register under § 162.153(i), the commenter, and other persons, will have adequate notification of registrations in which they have an interest.

Two commenters (Nos. 6 and 9) suggested that proposed § 162.153(h)(2) should be amended to allow States more than 45 days after issuance of a registration in which to send EPA a copy of final printed labeling for that registration. Both commenters stated that, in general, States cannot obtain copies of final printed labeling in time to comply with the 45 day limit. This accords with other comments received by EPA during the drafting of the proposed rule. EPA has therefore decided that, as suggested by some commenters, 60 days is a more reasonable time limit for submission of such labeling. Section 162.153(h)(2) has been amended accordingly.

One commenter (No. 16) criticized proposed § 162.153(d), which requires States to perform efficacy reviews only when registering public health uses, on the grounds that the requirement imposes an unfair burden on such registrants. EPA strongly disagrees with this comment. Although § 162.153(d) does place a burden on registrants of public health uses, the necessity of ensuring the efficacy of pesticides registered for such uses is clear and well-established. Lack of efficacy could have a direct and serious adverse impact on the health of persons who rely on such products for control of disease-causing pests. This is generally not the case for registration of other (e.g., agricultural) uses. Moreover, as stated in the preamble to the proposed rule, the efficacy review provision is consistent with EPA's general policy for registrations issued under sec. 3 of FIFRA (e.g., 40 CFR 162.182(b)(2)(i)).

One commenter (No. 9) objected generally to the proposed section on State registration procedures under § 162.152 on the grounds that they are not expressly authorized by FIFRA. The commenter suggested that State registration procedures be described in voluntary "guidelines" instead. EPA rejects this broad criticism since, for reasons stated in the preamble to the proposed rule (44 FR 46416), it is necessary to the implementation of EPA's duties under sec. 24(c) for all States to observe certain minimal uniform procedures. Only in this way can EPA be assured that States are exercising their authority in accordance with the limitations of sec. 24(c), and only by this type of regulation can EPA obtain the data needed to make reasonable decisions, when appropriate, on whether to disapprove State registrations or to suspend State authority. Therefore, such regulations are implicitly authorized by sec. 24(c) and sec. 25(a) of FIFRA.

Another commenter (No. 7) suggested that data required to be submitted to States by registrants under § 162.153 should be considered as "protected under FIFRA sec. 3(c)(1)(D) with respect to future use in support of registrations under sec. 3 of FIFRA." EPA cannot agree with this interpretation. The data protection provisions of sec. 3(c) specifically apply only to data submitted to the Administrator of EPA. Neither sec. 3(c)(1)(D) nor sec. 10, "Protection of Trade Secrets," was intended to apply to data held only by the States under sec. 24(c). As stated in the preamble to the proposed rules (44 FR 46416), valid registrations issued under sec. 24(c) are considered "registrations under sec. 3." However, the procedures leading up to registration by the State are not covered by the procedural requirements for issuance of registrations under sec. 3. This includes requirements under FIFRA for data use protection and compensation.

On another matter, one commenter (No. 16) objected to proposed § 162.153(d)(4) (now § 162.153(e)(5)) on the grounds that States are not authorized to classify pesticides for restricted use under FIFRA. This commenter has apparently misunderstood the clear intent and meaning of § 162.153(e)(5). That section does not allow States to classify pesticides for restricted use under FIFRA. It merely recognizes that many States have authority to classify pesticides under State law, and that it is possible that special conditions in a State may warrant a restriction of a pesticide use which is not restricted by EPA. States have always been free to impose such additional restrictions on pesticide use within their jurisdictions under sec. 24(a) of FIFRA, provided that they do not violate sec. 24(b) by altering the approved federal labeling or packaging in any way not specifically authorized by EPA. The agency has long

recognized and sanctioned such action by States, and § 162.153(e)(5) merely confirms this fact and lays down certain procedures which will ensure that States do not violate sec. 24(b) in exercising their authority. Of course, such an additional restriction under State law is enforceable only under State law, not under FIFRA sec. 3(d).

On a related topic, another commenter (No. 7) asked for clarification of a statement in the preamble to the proposed rule (44 FR 46417) to the effect that classification of a pesticide for restricted use by EPA will "automatically apply to all registrations previously issued under sec. 24(c) for that pesticide." As the commenter correctly observed, the preamble should have read that restriction of a use by EPA "will automatically apply to all registrations under sec. 24(c) for that use of the pesticide."

The same commenter also argued that proposed § 162.153(e)(3)(viii) was wrong in requiring that State supplemental labeling prohibit use of a pesticide inconsistent with EPA-approved labeling. The commenter claimed that this would largely negate the effect of sec. 24(c), since State supplemental labeling often authorizes uses inconsistent with the federal labeling. EPA disagrees with this assessment.

EPA recognizes that State supplemental labeling frequently authorizes uses not specifically authorized by EPA-approved labeling. That is consistent with the purpose of sec. 24(c). However, such additional uses also must be, and generally are, consistent with the federal labeling under the terms of FIFRA sec. 2(ee). That section allows many uses not found on the federal labeling, as long as the new use is not prohibited by the EPA labeling and is otherwise in conformance with sec. 24 and regulations thereunder. Therefore, State supplemental labeling can, and must, be written in such a way as to conform with approved federal labeling, as required by proposed § 162.153(e)(3)(viii). Readers should note, however, that proposed § 162.153(e)(3)(viii) has been combined with § 162.153(e)(3)(vii) in the final rule to eliminate some redundancy.

The same commenter also suggested that § 162.153(e) be expanded to provide additional guidance to States on supplemental labeling requirements in cases where a State registers an unclassified use of a pesticide for which other uses have been classified as restricted by EPA. EPA does not believe that such additional guidance is required since § 162.153(e)(3) already gives sufficient instruction as to the minimum required contents of any supplemental labeling. In any event, in many of the cases described by the commenter, the State will be required to classify the use registered under sec. 24(c) as restricted under § 162.153(g). In those instances where the State need not classify the use as restricted, it is free to indicate that fact on the supplemental labeling.

However, the Agency has, on its own initiative, slightly modified § 162.153(e)(3), and added a new § 162.153(e)(4), to clarify when State approved labeling must be made available to purchasers and users of pesticides registered under sec. 24(c), and to emphasize that the States have the primary responsibility for ensuring compliance with this requirement.

Commenter no. 7 also suggested that EPA publish a summary of all prior State registration actions in the first notice published under § 162.153(i). EPA has already compiled such a listing and has made it available to the States and to the public on microfiche.

Disapproval of State Registrations

One commenter (no. 7) suggested that § 162.153(c) be amended by changing the disapproval period for State registrations, for which EPA was not timely notified, from 90 days to 80 days from the time that EPA actually received notification of the registration. This suggestion was based on the commenter's belief that a disapproved registration remains in effect until the disapproval period is over, even though it may actually have been disapproved before the end of the disapproval period. The commenter was concerned that disapproved registrations should not remain effective longer than absolutely necessary. EPA shares this concern but does not agree with the commenter's suggestion, since it is based on an erroneous interpretation of sec. 24(c)(2). Disapprovals by EPA under that section are effective immediately, as § 162.154(c) clearly implies, unless the notice of disapproval indicates otherwise. This is the most reasonable interpretation of the statutory language. It is extremely unlikely that Congress intended that a State registration should be considered valid—and the pesticide to be lawfully distributed and used—after it has been disapproved on health, environmental, or other substantial grounds. Nothing in the legislative history of the section supports any interpretation other than EPA's. However, to avoid confusion on this subject, § 162.154(c) has been slightly amended to clarify this point.

Two commenters (nos. 7 and 12) also suggested that § 162.154(c) be amended to require the Administrator to include instructions on use or disposal of existing stocks of disapproved pesticides whenever appropriate. EPA agrees that such a change is reasonable and § 162.154(c) has been amended accordingly.

Finally, the U.S. Department of the Interior in its comments (no. 13) suggested that EPA consult the Fish and Wildlife Service whenever making a determination under § 162.154(a)(1)(i) on the possible creation of unreasonable adverse effects on the environment. Although EPA must retain sole responsibility for making such decisions under § 162.154, the Agency intends to consult with other Agencies whenever appropriate to obtain expert advice on matters with which the other Agencies are concerned.

Suspension of State Authority

One commenter (no. 16) suggested that § 162.155(b)(2) and (c)(3) be amended to require the Administrator to suspend a State's authority whenever a State commits any of the acts described therein. EPA rejects this suggestion since it would deprive the Administrator of the discretion, expressly granted by sec. 24(c)(4), which is needed in order to negotiate reasonable solutions with States in cases where suspension of State authority is not necessary.

Similarly, EPA must partially reject another commenter's (no. 8) claim that § 162.155(b)(2) allows the Administrator too much discretion in that it authorizes suspension for a State's refusal to correct "other deficiencies in its program specified by the Administrator." This authority is consistent with sec. 24(c)(4) and is necessary to ensure that State programs are implemented in accordance with sec. 24(c). However, EPA agrees that the term "other deficiencies" is somewhat broad and § 162.155(b)(2) has therefore been revised to limit the Administrator's power to cases of "significant deficiencies" in the State program.

Finally, the same commenter also suggested that § 162.155 be amended to specify the administrative or judicial remedies which are available to a State subject to a suspension of its authority. EPA agrees with this request and § 162.155 has been modified to specify that remedies are available under sec. 16 of FIFRA and the Administrative Procedure Act.

In addition, § 162.155(c) has been revised to clarify the procedures by which final decisions on suspension will be made, including procedures for administrative hearings and appeals.

Miscellaneous

One commenter (no. 7) requested that the rules be revised to state expressly that sec. 24(c) registrants must comply with State law as well as all applicable federal laws and regulations. EPA does not believe such an amendment is required since it is clear that all State laws and regulations which are not in conflict with FIFRA, or rules thereunder, must be obeyed by those under the jurisdiction of the State.

Another commenter (no. 8) objected to the statement in the preamble to the proposed rule (44 FR 46417) that disapprovals by EPA of registrations under sec. 24(c) are not the same as denial, suspension, or cancellation of registrations under sec. 3 and 6 of FIFRA. The commenter argued that disapprovals are equivalent to such actions, and that State registrants subject to disapproval are entitled to remedies under sec. 3, 6 and 15 of FIFRA. EPA rejects this argument absolutely since the language of sec. 24(c) itself clearly distinguishes between disapprovals and other actions taken under FIFRA and establishes procedures for disapproval different from procedures established for sec. 3 and 6. Nor is there any indication in either sec. 3 or 6, or their legislative history, that disapproval of State registrations is to be covered by the procedures established expressly for denial, suspension, and cancellation of registrations.

Two commenters (nos. 5 and 9) objected that proposed § 162.156(a)(3), stating that registrations not issued in accordance with § 162.156(a) and (b) are invalid, was unauthorized under sec. 24(c). EPA strongly disagrees with this interpretation for the reasons stated in the preamble to the proposed rule (44 FR 46418). Even though sec. 24(c) does not expressly refer to invalidation of State registrations, it does specifically lay down several important prerequisites to the issuance of registrations by a State under that section. § 162.156(a) and (b) restate and clarify those conditions. A State registration which does not meet all of those prerequisites clearly cannot be considered valid under sec. 24(c). It would be unreasonable, for example, to conclude that a registration issued by a State for a pesticide use previously cancelled by EPA should be considered valid even though sec. 24(c)(1) expressly prohibits such registrations. The unreasonableness of considering such potentially hazardous unauthorized registrations as valid until disapproved is further demonstrated by the fact that EPA's authority to disapprove State registrations is relatively limited. Therefore, § 162.156(a)(3) is a necessary, proper, and authorized way to prevent pesticides which are registered in flagrant violation of sec. 24(c)(1), but which are beyond EPA's disapproval authority, from entering into public use. However, EPA does recognize that proposed § 162.156(a)(3) was somewhat overbroad in that it incorporated as grounds for invalidation all of § 162.152(b), even though some provisions of the latter section were not limitations on State authority created by sec. 24(c). Accordingly, § 162.156(a)(3) has been revised to incorporate by reference only those parts of § 162.152(b) derived from the limitations found in sec. 24(c).

On the same topic, another commenter (no. 6), implicitly conceding the legitimacy of § 162.152(a)(3), suggested that a 90 day limit be placed on the Administrator's authority to issue notices of invalidity. EPA must also reject this suggestion, which was apparently based on the fact that there is a 90 day limit on EPA's disapproval authority. As explained above, invalidation and disapproval are of entirely different natures. The procedural restraints expressly imposed on disapproval actions by sec. 24(c) are not, and should not be, imposed on notices of invalidation which merely point out that a particular registration is void, from the moment it was issued, under the direct operation of sec. 24(c) itself. However, pursuant to another commenter's request (no. 16), § 162.156(a)(3) has been slightly modified to require the Administrator to notify the registering State whenever he discovers that a State registration is invalid.

Finally, one commenter (no. 2) suggested that the five year limit for completion of a regulatory review under sec. 2(d)(8) of Executive Order 12044, proposed for this rule (44 FR 46418), be shortened to two and one-half years. EPA must reject this suggestion. The five year review period is standard for this type of regulation, while the period proposed by the commenter is too short to permit an accurate evaluation of the effectiveness of this rule. However, it should be noted that the regulation is subject to amendment at any time if a need for such action can be shown. The commenter and other interested persons, are, of course, free to bring such a need to EPA's attention whenever it arises.

Several other comments were received which were either irrelevant or clearly erroneous in content, or which were too minor to warrant discussion in this preamble.

Conclusion

As the preceding discussion shows, relatively few changes in the proposed regulations were necessary. Those changes are either minor or made pursuant to specific proposals on which public comment was invited in the preamble to the proposed rule. Therefore, this regulation does not require reproposal under 5 U.S.C. 553(b).

Regulatory Analysis

EPA has determined that this rule does not require a Regulatory Analysis under Executive Order 12044. A screening study to this effect is available for review.

Statutory Review

The U.S. Department of Agriculture has reviewed this regulation in accordance with section 25(a) of FIFRA and has concurred with only one minor comment in its publication in the Federal Register. That comment involved clarification of § 162.152(a)(2) and the comment has been incorporated in this final rule.

The regulation was also submitted for scientific review and comment to the FIFRA Scientific Advisory Panel (SAP) in accordance with section 25(d) of FIFRA. In a letter dated August 20, 1980 to the EPA Deputy Assistant Administrator for Pesticide Programs, the SAP concurred without comment in the proposed regulation.

Regulatory Review

Section 2(d)(8) of Executive Order 12044 requires that a plan for evaluating the regulation after its issuance be developed. The Agency's plan for evaluation of this rule calls for an analysis by EPA of the regulation and its effect on State regulatory agencies and registrants, in cooperation with the State-FIFRA Issues Research and Evaluation Group.

This evaluation will be performed within five years from the date of promulgation of this rule, and a determination will then be made as to whether modification of the rule is necessary.

Effective Date: On December 17, 1980, President Carter signed the Federal Insecticide, Fungicide, and Rodenticide Act Extension bill (Pub. L. 96-539). This bill amended several sections of FIFRA, including sec. 25 on rulemaking. Section 4 of the Extension Act adds a new paragraph, sec. 25(e), to FIFRA which requires EPA to submit final regulations to Congress for review before the regulation becomes effective. Copies of this rule have been transmitted to

appropriate offices in both Houses of Congress.

(FIFRA 24(c); 7 USC 136v)
Dated: December 24, 1980.

Douglas M. Costle,
Administrator.

Pursuant to sec. 4 of the 1980 FIFRA Extension Act, and in accordance with President Carter's statement on signing the bill (Weekly Compilation of Presidential Documents, p. 2814, December 22, 1980), this rule will not take effect before the end of 60 calendar days of continuous session of Congress after the date of publication of this rule. Since the actual length of this waiting period may be affected by Congressional action, it is not possible, at this time, to specify a date on which this regulation will become effective. Therefore, EPA at the appropriate time, will publish a notice in the Federal Register. announcing the end of this "report and wait" period and notifying the public of the actual effective date of this regulation.

40 CFR Part 162 is amended by reserving Subparts B and C and establishing Subpart D, to read as follows:

PART 162—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

* * * * *

Subparts B-C—[Reserved]

Subpart D—Regulations Pertaining to State Registration of Pesticides To Meet Special Local Needs

Sec.
162.150 General.
162.151 Definitions.
162.152 State registration authority.
162.153 State registration procedures.
162.154 Disapproval of State registrations.
162.155 Suspension of State registration authority.
162.156 General requirements.

Authority. Sec. 24(c) and 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA or the Act (secs. 22 and 23, Pub. L. 95-396, 92 Stat. 819; 7 U.S.C. 136 et seq.)

Subparts B-C—[Reserved]

Subpart D—Regulations Pertaining to State Registration of Pesticides To Meet Special Local Needs

§ 162.150 General.

(a) *Scope.* This subpart sets forth regulations governing the registration by any State of pesticide products, or uses thereof, formulated for distribution and use within the State to meet special local needs under sec. 24(c) of the Act. It also sets forth regulations governing the exercise by the Administrator of the power to disapprove specific State registrations and to suspend a State's registration authority under sec. 24(c). Unless otherwise indicated, any reference herein to registrations issued by a State includes amendments of registrations issued by States.

(b) *Applicability.* This subpart applies only to State registration authority granted by sec. 24(c) of FIFRA. It does not apply to any authority granted, or procedures established, by State law with respect to registration, licensing, or approval required for use within the State of federally registered pesticide products. In addition, this subpart does not apply to products or uses registered by a State prior to August 4, 1975, and which have continued in intrastate commerce in accordance with § 162.17, unless those products were subsequently registered by the State under sec. 24(c).

§ 162.151 Definitions.

Unless otherwise indicated, terms used in this subpart have the meanings set forth in FIFRA and in Subpart A of this part. In addition, as used in this subpart, the following terms have the meanings set forth below: (a) "Federally registered" means currently registered under sec. 3 of the Act, after having been initially registered under the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (Pub. L. 86-139; 73 Stat. 286; June 25, 1947) by the Secretary of Agriculture or under FIFRA by the Administrator.

(b) "Manufacturing-use product" means any pesticide product other than a product to be labeled with directions for end use. This term includes any product intended for use as a pesticide after re-formulation or repackaging.

(c) "New product" means a pesticide product which is not a federally registered product.

(d) "Pest problem" means (1) a pest infestation and its consequences, or (2) any condition for which the use of plant regulators, defoliants, or desiccants would be appropriate.

(e) "Product" or "pesticide product" means a pesticide offered for distribution and use, and includes any labeled container and any supplemental labeling.

(f) "Similar composition" refers to a pesticide product which contains only the same active ingredient(s), or combination of active ingredients, and which is in the same category of toxicity, as a federally registered pesticide product.

(g) "Similar product" means a pesticide product which, when compared to a federally registered product, has a similar composition and a similar use pattern.

(h) "Similar use pattern" refers to a use of a pesticide product which, when compared to a federally registered use of a product with a similar composition, does not require a change in precautionary labeling under § 162.10(h), and which is substantially the same as the federally registered use. Registrations involving changed use patterns are not included in this term.

(i) "Special local need" means an existing or imminent pest problem within a State for which the State lead agency, based upon satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available.

(j) "State" or "State lead agency" as used in this subpart means the State agency designated by the State to be responsible for registering pesticides to meet special local needs under sec. 24(c) of the Act.

§ 162.152 State registration authority.

(a) *Statutory limitations.* In accordance with sec. 24(c) of the Act, each State is authorized to register a new end use product for any use, or an additional use of a federally registered pesticide product, if the following conditions exist: (1) There is a special local need for the use within the State;

(2) The use is covered by necessary tolerances, exemptions or other clearances under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346 et seq.), if the use is a food or feed use;

(3) Registration for the same use has not previously been denied, disapproved, suspended or cancelled by the Administrator, or voluntarily cancelled by the registrant subsequent to issuance by the Administrator of a notice of intent to cancel that registration, because of health or environmental concerns about an ingredient contained in the pesticide product, unless such denial, disapproval, suspension or cancellation has been superseded by subsequent action of the Administrator; and

(4) The registration is in accord with the purposes of FIFRA.

(b) *Types of registrations—(1) Amendments to federal registrations.*

(i) Subject to the provisions of paragraphs (a) and (b)(1)(ii)(iv) of this section, States may register any new use of a federally registered pesticide product.

(ii) A State may register any use of a federally registered product for which registration of other uses of the product was denied, disapproved, suspended, or

cancelled by the Administrator, provided that the State may register a use not considered by the Administrator in reaching such a determination only after the State consults with appropriate EPA personnel.

(iii) Except as provided in paragraph (a)(3) of this section, a State may register any use of a federally registered product for which registration of some or all uses has been voluntarily cancelled by the registrant, provided that a State may register such a use only after the State has consulted with appropriate EPA personnel.

(iv) A State may not register an amendment to a federally registered manufacturing-use product.

(2) *New products.* (i) Subject to the provisions of paragraph (a) and subparagraphs (b)(2) (ii) and (iii) of this section, a State may issue registrations to meet special local needs for the following types of new end-use products: (A) A product which is identical in composition to a federally registered product, but which has differences in packaging, or in the identity of the formulator.

(B) A product which contains the same active and inert ingredients as a federally registered product, but in different percentages.

(C) Subject to the requirements of paragraph (b)(2)(ii) of this section, a product containing a new combination of active, or active and inert, ingredients.

(ii) A State may register a new product only if each of the active ingredients in the new product is present because of the use of one or more federally registered products and if each of the inert ingredients in the new product is contained in a federally registered product.

(iii) A State may not register a new manufacturing-use product.

(iv) A State may register any use of a new product containing an ingredient described in paragraph (a)(3) of this section, if the new product registration is for a formulation or a use not included in the denial, disapproval, suspension, or cancellation, or if the federally registered use was voluntarily cancelled without a prior notice of intent to cancel by the Administrator. However, a formulation or use of such a new product which was not considered by the Administrator during such proceedings, or which was not the subject of a notice of intent to cancel, may be registered by a State only after the State consults with appropriate EPA personnel regarding the registration application.

(c) *Effect of State registration.* (1) A State registration issued under FIFRA sec. 24(c) which meets the conditions described in paragraphs (a) and (b) of this section, and which is not disapproved by the Administrator under § 162.154, shall be considered a federal registration, but shall authorize distribution and use only within that State. Accordingly, such registrations are subject to all provisions of FIFRA which apply to currently registered products, including provisions for cancellation and suspension of registrations, and reregistration of products.

(2) A State may require, as a condition of distribution or use of a pesticide product within the State, that the pesticide product be registered under State law as well as under FIFRA. Neither FIFRA sec. 24(c) nor §§ 162.150–162.156 affects a State's right under its own law to revoke, suspend, cancel, or otherwise affect such a registration issued under State law. However, the federal registration, whether issued under FIFRA sec. 3 or 24(c), is not affected by such a State action.

§ 162.153 State registration procedures.

(a) *Application for registration.* States shall require all applicants for registration to submit the following information: (1) Name and address of the applicant and any other person whose name will appear on the labeling or in the directions for use.

(2) The name of the pesticide product, and, if the application is for an amendment to a federally registered product, the EPA registration number of that product.

(3) A copy of proposed labeling, including all claims made for the product as well as directions for its use to meet the special local need, consisting of: (i) For a new product, a copy of the complete proposed labeling; or,

(ii) For an additional use of a federally registered product, a copy of proposed supplemental labeling and a copy of the labeling for the federally registered product.

(4) The complete formula of the product, if the application is for a new product registration.

(5) Any other information which is required to be reviewed prior to registration under this section.

(b) *Special local need determination.* In reviewing any application for registration, the State shall determine whether there is a special local need for the registration. Situations which a State may consider as not involving a special local need may include, but are not limited to, applications for registrations to control a pest problem present on a nationwide basis, or for use of a pesticide product registered by other States on an interregional or nationwide basis.

(c) *Unreasonable adverse effects determination.* (1) Prior to issuing a registration in the following cases, the State shall determine that use of the product for which registration is sought will not cause unreasonable adverse effects on man or the environment, when used in accordance with labeling directions or widespread and commonly recognized practices: (i) For use of a product which has a composition not similar to any federally registered product.

(ii) For use of a project involving a use pattern not similar to any federally registered use of the same product or of a product with a similar composition.

(iii) For use of a product for which other uses of the same product, or of a product with a similar composition, have had registration denied, disapproved, suspended, or cancelled by the Administrator.

(2) Determinations required by paragraph (c)(1) of this section shall be based on data and criteria consistent with those sections of subpart A of this part, and of Part 163 of this chapter, applicable to the type of product or use under consideration. Such determinations may also involve consideration of the effect of the anticipated classification of the product or use under § 162.153(h).

(d) *Efficacy determination.* Prior to registration of any use of a product for public health purposes—that is, a use which could result in substantial harm to the public health if the product does not perform its intended function, the State shall determine that the product warrants the claims made for it in the registration application. Such determinations shall be based on criteria specified in applicable sections of subpart A and of Part 163 and on any additional criteria established by the State.

(e) *Labeling requirements.* (1) Prior to issuing any registration, the State shall review the proposed labeling submitted with the application to determine compliance with this paragraph. In addition, the State shall review a copy of the final printed labeling as soon as practical after a registration is issued in order to verify compliance with this paragraph.

(2) For a new product, the State must, as a condition of the registration, require that the product be accompanied from the time it enters the stream of commerce by labeling meeting all applicable criteria of § 162.10. New product labeling must all contain: (i) A

statement identifying the State where registration is to be valid.

(ii) The special local need registration number assigned by the State.

(3) Except as provided in paragraph (e)(4) of this section, as a condition for a registration of an additional use of a federally registered product, the State must require that at the time of sale to users, labeling from the federally registered product be accompanied by supplemental labeling which contains:

(i) A statement identifying the State where registration is valid.

(ii) Directions for use to meet the special local need which satisfy the criteria of § 162.10(i).

(iii) The trade name of the product.

(iv) The name and address of the section 24(c) registrant.

(v) The EPA registration number of the federally registered product.

(vi) The special local need registration number assigned by the State.

(vii) A statement prohibiting use of the product in a manner inconsistent with all applicable directions, restrictions, and precautions found in the labeling of the federally registered product and accompanying supplemental labeling.

(4) When a federally registered product is already in the stream of commerce at the time the State issues a registration for an additional use of that product, the State must ensure that supplemental labeling for the additional use, meeting the criteria of paragraph (e)(3) of this section, is made available to purchasers and users of the product within 45 days of the date on which the State approves the final printed supplemental labeling.

(5) If a State classifies for restricted use a product or use registered by the State, which is not required to be so classified by paragraph (g) of this section, then the State may require supplemental labeling for the product or use containing additional appropriate precautions, and a statement that the product or use is for restricted use within that State.

(f) *Packaging and coloration standards.* All products registered by a State must meet all appropriate packaging standards prescribed by the Administrator under sec. 25(c)(3) of FIFRA. State registered products must also meet all appropriate standards for coloration, or discoloration, established by regulation under sec. 25(c) of FIFRA, including the standards contained in § 162.13. Prior to issuing any registration, the State shall determine that the product will conform to these requirements.

(g) *Classification.* (1) As part of the registration of any product or use, a State shall classify the product or use as a restricted use pesticide if: (i) The product is identical or similar in composition to a federally registered product: (A) For which all federally registered uses have been classified as restricted by the Administrator; or

(B) For which a use similar to the State registered use has been classified as restricted by the Administrator; or

(ii) The State registered product or use meets the criteria for classification as a restricted use pesticide under the applicable provisions of § 162.11(c) (1) through (4).

(h) *Notification and Submission of Data.* (1) Within ten working days from the date a State issues, amends, or revokes a registration, the State shall notify EPA, in writing, of the action. Notification of State registrations, or amendments thereto, shall include the effective date of the registration or amendment, a confidential statement of the formula of any new product, and a copy of the draft labeling reviewed and approved by the State, provided that labeling previously approved by the Administrator as part of a federal registration need not be submitted.

(2) Notification of State registrations or amendments shall be supplemented by the State sending to EPA a copy of the final printed labeling approved by the State within 60 days after the effective date of the registration or amendment.

(3) Notification of revocation of a registration by a State shall indicate the effective date of revocation, and shall state the reasons for revocation.

(4) The Administrator or his designee may request, when appropriate, that a State submit to EPA any data used by the State to determine that unreasonable adverse effects will not be caused when the State registers any use described in paragraph (c)(1) of this section. Within 15 working days of receipt of such a request from EPA, the State shall submit two copies of the requested data.

(i) *Federal Register Publication.* The Administrator shall publish in the Federal Register, on a regular basis, a summary of all State registrations made under sec. 24(c) during a previous reporting period established by the Administrator. For each product or use registered, the notice shall indicate:

(1) The name of the product.

(2) The name of the registrant.

(3) The registered use(s) of the product.

(4) The effective date of the State registration.

(5) If the registration is for an additional use of a federally registered product, whether the State registration involves a changed use pattern.

§ 162.154 Disapproval of State registrations.

(a) *General disapprovals.* (1) Except as provided in paragraph (b) of this section, the Administrator may disapprove, on any reasonable grounds, any state registration which, when compared to a federally registered product, does not have both a similar composition and a similar use pattern; provided that the Administrator may not disapprove such a registration solely because of a lack of essentiality. Grounds for disapproval of State registrations not involving similar products may include, but are not limited to: (i) Probable creation of unreasonable adverse effects on man or the environment by the registered use.

(ii) Refusal of the registering State to submit information supporting the registration as required by § 162.153(h).

(iii) Failure of information submitted by the State to support the State's decision to issue the registration under standards established by § 162.153.

(2) Prior to disapproval of any State registration under this paragraph, the Administrator shall notify the registering State, in writing, of the Administrator's intent to disapprove, and of the reasons for disapproval. The notice of intent will provide a reasonable time, not less than ten days from the date the notice is received by the State, for the State to respond, and will invite the State to consult with the Administrator or his designee. If the grounds for disapproval are based on actions or omissions by the State, the notice will, if possible, also provide the State with a reasonable amount of time in which to take corrective action, not to exceed the time allowed for disapproval under paragraph (c) of this section.

(3) The registering State may, within ten days of receipt of a notice of intent to disapprove, request that the Administrator, or his designee, consult with appropriate State officials prior to the Administrator's final decision on disapproval. The Administrator will consider any relevant information presented at such a consultation, or in any other timely and appropriate fashion, in deciding whether to withdraw the notice of intent to disapprove.

(b) *Special disapprovals.* (1) The Administrator may disapprove any State registration, including a registration for a similar product, at any time, if the Administrator determines that use of the product under the State registration: (i) Would constitute an imminent hazard.

(ii) May result in a residue on food or feed exceeding, or not covered by, a tolerance, exemption, or other clearance

under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346a et seq.).

(2) If the Administrator disapproves a registration under this paragraph, the Administrator shall provide the registering State with written notification of disapproval, in accordance with paragraph (c) of this section, as soon thereafter as practicable. Such notification will specify the grounds for disapproval and invite the State to comment on the decision.

(3) If requested by the State within ten days of its receipt of a notice of disapproval, the Administrator, or his designee, will consult with appropriate State officials. The Administrator may consider any information presented at such a consultation, or in any other appropriate fashion, in determining whether the disapproval should be rescinded.

(c) *Decision and notification of disapproval.* Except as provided in paragraph (b)(1) of this section, the Administrator will make a final decision on disapproval of a State registration, and provide written notification thereof to the State, within 90 days of the effective date of the registration; provided that, if the State does not notify the Agency of a registration within ten days of its effective date, then the Administrator will make a final decision on disapproval within 90 days of the date on which EPA receives notification of the State registration. The notice of disapproval will specify an appropriate date on which the disapproval will become effective. Disapproval may become effective immediately, or at anytime within the period allowed for the Administrator to make a final decision on disapproval. The notice of disapproval will also, when appropriate, give instructions for use or disposal of the pesticide. Each notice of disapproval will be published in the Federal Register.

(d) *Effect of disapproval.* If a registration issued by a State is disapproved by the Administrator, that registration will not be valid for any purpose under FIFRA, as of the date the disapproval becomes effective. Thereafter, distribution or sale of the pesticide, in either interstate or intrastate commerce, for uses subject to the disapproval will be a violation of sec. 12(a)(1) of FIFRA.

(e) *Recission of disapproval.* If the Administrator determines, after consultation with the State lead agency, that a registration, previously issued by the State and disapproved by the Administrator, should not have been disapproved under FIFRA, then the Administrator shall rescind the disapproval. The Administrator shall send written notification of the rescission to the State. In addition, the Administrator shall publish notice of any rescission of disapproval in the Federal Register.

(f) *Notification of registrants.* Any State that issues a registration which has been disapproved, or which is subject to a notice of intent to disapprove, shall be responsible for notifying the affected registrant of any such notice of intent or disapproval, and of any recession of disapproval by the Administrator.

§ 162.155 Suspension of State registration authority.

(a) *General.* (1) If the Administrator finds that a State is not capable of exercising, or has failed to exercise, adequate control over its registration program, so that the State cannot ensure that registrations issued by it will be in accord with the purposes of FIFRA, then the Administrator may suspend the State's authority to register pesticides under sec. 24(c) of the Act. Registrations issued by the State after suspension of its authority will not be considered valid under FIFRA. Registrations issued by the State prior to suspension will not be affected by the suspension.

(2) The Administrator may suspend all or any part of a State's registration authority, as appropriate.

(b) *Grounds for Suspension.* (1) The Administrator may suspend a State's registration authority due to lack of, or failure to exercise, adequate control by the State over its sec. 24(c) registration program. Adequate control includes, but is not limited to, all of the following: (i) Access to appropriate scientific and technical personnel to review data and make determinations as required by § 162.153.

(ii) Registration procedures satisfying § 162.153.

(iii) Complete and accurate records of State registrations.

(iv) Adequate legal authority: (A) To deny, suspend, revoke, or amend a State registration when the registration is not in compliance with FIFRA, this subpart, or State law, or when necessary to prevent unreasonable adverse effects on the environment.

(B) To enter, at reasonable times, by consent, warrant, or other legal means, any establishment where pesticides are produced or held for distribution or sale, to inspect, sample, and observe whether pesticides are being produced or distributed in compliance with FIFRA, this subpart, State law, and the terms of any State registration.

(2) The Administrator may suspend a State's registration authority if the State fails to exercise the controls specified in paragraph (b)(1) of this section, or if the State refuses to correct within a reasonable time any other significant deficiencies in its regulatory program, as specified by the Administrator in a notice of intent to suspend.

(c) *Procedures for Suspension.* (1) Prior to suspending the registration authority of any State, the Administrator will notify the State lead agency, in writing, of the Administrator's intent to suspend, and of the specific grounds for suspension. The notice of intent will specify whether the suspension will be complete or partial, and will provide the State an opportunity to respond and a reasonable amount of time, not less than 30 days from the date the notice is received, in which to correct the deficiencies specified in the notice. If the State does not correct the specified deficiencies within the reasonable time allowed by the notice, or if the Administrator has not withdrawn the notice of intent before that time, the notice of intent will be published in the Federal Register, and the public given an opportunity to comment thereon.

(2) If requested by the affected State lead agency within 30 days of receipt of the notice of intent to suspend, an informal consultation between appropriate State and EPA officials will be held to discuss the proposed suspension. In such a case, the Administrator shall not make a final decision on the proposed suspension until after the consultation. The Administrator shall consider all relevant information presented at the consultation, or in any other appropriate manner, in determining whether to suspend the State's authority. If the Administrator determines, on the basis of such information, that the deficiencies listed in the notice of intent no longer exist, or will be corrected in a reasonable time, then the Administrator will withdraw, in writing, the notice of intent to suspend.

(3) Within ten days of the date a notice of intent to suspend is published in the Federal Register, a State may request a public hearing to consider the proposed suspension. If a hearing is requested, the Administrator will:

(i) Schedule a public hearing to be held in that State.

(ii) Publish in the Federal Register a notice announcing the date, time, and location of the hearing.

(iii) Appoint a presiding officer who shall preside over the hearing.

(iv) Prescribe additional, appropriate procedures for the conduct of the hearing, including procedures for the presentation of relevant material evidence from the State, EPA, or

members of the public who would be affected by the outcome of the hearing. Evidence may be presented in either oral or written form, at the discretion of the Administrator.

(4) Following the close of any hearing held under paragraph (c)(3) of this section, the presiding officer shall make a recommended decision that the State's authority to register pesticides under sec. 24(c) of FIFRA be suspended, in whole or in part, or that the State's authority not be suspended and that the notice of intent to suspend be withdrawn.

(5) Any recommended decision made by a presiding officer under paragraph (c)(4) of this section may be appealed to the Administrator within 30 days after its issuance by the State or by EPA. Any recommended decision which is not appealed, or which the Administrator does not review on his own initiative, will become a final Agency action 30 days after its issuance.

(6) If no hearing is requested under paragraph (c)(3) of this section, or if a recommended decision is appealed to the Administrator under paragraph (c)(5) of this section, the Administrator shall issue a final order either suspending the State's authority to register pesticides under section 24(c) of FIFRA, in whole or in part, or withdrawing the notice of intent to suspend.

(7) Any final order suspending State registration authority, issued under paragraph (c) (5) or (6) of this section, will specify the grounds therefor and an effective date for the suspension. If the suspension is merely partial, the notice of suspension will specify the types of registrations which will not be recognized as valid under sec. 24(c). All final orders issued under paragraph (c) (5) or (6) will be published in the Federal Register.

(d) *Termination of suspension.* Suspension of a State's authority will be effective for the period specified in the notice of suspension, or if no period was specified, until such time as the Administrator is satisfied that the State can and will exercise adequate control over its program. In the latter case, the Administrator will notify the State that the suspension is terminated, or that it will be terminated on a specific date. In either case, the Administrator will publish a notice of the termination of suspension in the Federal Register.

(e) *Judicial review.* Any State whose authority to register pesticides has been finally suspended by the Administrator may seek judicial review of the Administrator's decision under sec. 16 of FIFRA, at any time prior to termination of the suspension. Such suspension shall remain in effect during the period of judicial review unless otherwise ordered by the Administrator.

§ 162.156 General requirements.

(a) *Requirements for distribution and use.* (1) Any product whose State registration has been issued in accordance with §§ 162.152 and 162.153 may be distributed and used in that State, subject to the following provisions of the Act and the regulations promulgated thereunder:

(i) Sec. 12(a)(1) (A) through (E), in accordance with:

(A) Sec. 2(q)(1) (A) through (G).

(B) Sec. 2(q)(2) (A) through (D).

(ii) Sec. 12(a)(2) (A) through (G) and (I) through (P).

(2) A product or use classified by a State for restricted use under § 162.153(g) may be used only by, or under the direct supervision of, an applicator certified under a plan approved by EPA in accordance with sec. 4 of FIFRA.

(3) State registrations which are not issued in accordance with § 162.152 (a) and (b)(2) (i), (ii) and (iii) are not authorized by section 24(c) and are not considered valid for any purposes under FIFRA. When the Administrator determines that a registration is invalid, the Administrator shall notify the registering State that the registration is invalid, and may specify the reason for the invalidity.

(b) *Establishment registration requirements.* No person may produce any pesticide, including any pesticide registered by a State under section 24(c), unless the establishment in which it is produced is registered by the Administrator in accordance with sec. 7 of FIFRA and 40 CFR Part 167.

(c) *Books and records requirements.* All producers of pesticides, including those producers of pesticides registered by States under sec. 24(c), must maintain records in accordance with the requirements imposed under sec. 8 of FIFRA and 40 CFR Part 169.

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